IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

GINA LLOYD, **Plaintiff,** **v.** **MEDTRONIC, INC., MEDTRONIC USA, INC., MEDTRONIC LOGISTICS, LLC, and MEDTRONIC PUERTO RICO OPERATIONS CO.,** **Defendants.**	**Case No. 20-CV-01156-SPM**

MEMORANDUM AND ORDER

McGLYNN, District Judge:

Plaintiff Gina Lloyd filed this products liability action against Defendants Medtronic, Inc., Medtronic USA, Inc., Medtronic Logistics, LLC, and Medtronic Puerto Rico Operations Co. (hereinafter "Medtronic") claiming she sustained injuries from Medtronic's defective SynchroMed II Programmable Implantation Infusion Pump System (Doc. 4, pp. 1, 5-6, 28-9, 35). Pending before the Court is Medtronic's Motion to Dismiss ("MTD") the Complaint and a memorandum in support of dismissal (Doc. 16). For the reasons set forth below, the Motion is granted in part and denied in part.

FACTUAL & PROCEDURAL BACKGROUND

The following facts are taken from Lloyd's Complaint and the Court views them as true for the purposes of this motion. The SynchroMed II (hereinafter the "device") is a Class III medical device that functions as a drug infusion system and is

implanted in the body, remaining there for drug delivery (Doc. 4, pp. 3-4). The device includes an infusion pump, which enables storage and drug delivery, connected to a thin, flexible catheter for intrathecal space (spinal canal) infusion (*Id.* at 3). The United States Food and Drug Administration approved the device through the Premarket Approval process in September 2003 (*Id.* at 3). The device is approved for the following uses:

- The chronic infusion of Infumorph (preservative-free morphine sulfate sterile solution) in the treatment of chronic intractable pain.
- The chronic infusion of Prialt (preservative-free ziconotide sterile solution) for the management of severe chronic pain.
- The chronic infusion of Lioresal Intrathecal (baclofen injection) in the management of severe spasticity.

Since Premarket Approval, the FDA has identified deviations in pump manufacturing that could lead to underinfusion of the drugs contained in the reservoir (*Id.* at 18, 20, 34). The device and its components have also been subject to no fewer than 72 recalls, including recalls for motor stall related to the pump which caused underinfusion of the drugs contained in the reservoir (*Id.* at 23-4, 35).

Lloyd is a fifty-five-year-old woman experiencing pain resulting from cervical post-laminectomy syndrome, as well as pain of the low back and the extremities from peripheral neuropathy (Doc. 4, p. 5). In January 2015, to treat her pain, Lloyd underwent a surgical implantation of the device to administer a continuous intrathecal dose of Dilaudid, Clonidine, and bupivacaine (*Id.* at 6-7).

Beginning in April 2018, Lloyd complained of pain (*Id.* at 6). In August 2018, Lloyd had a new catheter implanted because of a kink or blockage in her first catheter (*Id.*).

Lloyd's pain continued and her physicians concluded that her pump had malfunctioned (*Id.* at 6-7). In January 2019, her surgeon removed the malfunctioning pump mechanism and implanted a new pump (*Id.* at 7). In May 2019, Lloyd again complained of pain to her physicians and she states that she continues to receive little pain relief from her new pump (*Id.*).

Lloyd concludes that the pump mechanisms for the device implanted in her failed to deliver medication as intended (*Id.* at 7). As a result, she suffered damages from pain and suffering; mental anxiety and anguish; pump removal and replacement; and medical bills (*Id.*). Lloyd asserts Illinois state-law claims for strict liability (Counts I and III), negligence (Counts II, IV, and V) and punitive damages (Count VIII) against Medtronic (*Id.* at 32-48).[1] Lloyd bases her state-law strict liability claim in Count I and negligence claim in Count II on violations of 21 C.F.R. 820.30 *et seq.,* which describe the Quality Control Requirements of the Current Good Manufacturing Practices of the FDA.

LEGAL STANDARD

To survive a motion to dismiss, the complaint must state sufficient "facts to state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). In other words, the plaintiff must provide enough "factual enhancement" to "[nudge] their claims across the line from conceivable to plausible .

[1] Lloyd withdrew her breach of warranty claims (Counts VI and VII) (Doc. 17, p. 2).

. . ." *Id.* at 547. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 566 U.S. 662, 678 (2009).

When applying this standard, the court must "accept as true all factual allegations in the amended complaint and draw all permissible inferences in [the non-moving plaintiff's] favor." *Bible v. United Student Aid Funds, Inc.,* 799 F.3d 633, 639 (7th Cir. 2015). In fact, "a well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable, and that a recovery is very remote and unlikely." *Alam v. Miller Brewing Co.,* 709 F.3d 662, 666 (7th Cir. 2013), *quoting Twombly,* 550 U.S. at 556. However, allegations that merely state "legal conclusions" or "[t]hreadbare recitals of the elements of a cause of action" are not entitled to this assumption of truth. *Ashcroft v. Iqbal*, 566 U.S. at 678.

ANALYSIS

Medtronic argues that the Complaint should be dismissed because the claims are preempted by federal law, the Complaint does not satisfy the pleading standard in Federal Rule of Civil Procedure 8(a), and the claims fail under state law (Doc. 16, p. 1). Lloyd disagrees, contending that her claims are parallel and survive under the pleading standard.

To determine whether the claims are preempted, the Court must conduct the two-part test explained in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). In *Riegel*, the Supreme Court addressed the scope of preemption under the Medical Device Amendments to the Food, Drug and Cosmetic Act ("MDA"), as applied to Class III medical devices that have obtained Premarket Approval. The MDA preempts state

requirements that are different or in addition to federal requirements; therefore, a court must first determine whether any federal requirements are applicable to the medical device. *Id.* at 321–22 (citing 21 U.S.C. § 360k(a)). To satisfy this part of the test, the federal requirement must be specific to the device and not simply reflect "concerns about device regulation generally." *Id.* at 322 (quoting *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 501 (1996)).

If federal requirements exist, the court must then determine whether a plaintiff's claims rely upon state law requirements that are "different from, or in addition to" the applicable federal requirements and whether the state law "relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device." *Riegel*, 552 U.S. at 323 (quoting 21 U.S.C. § 360k(a)). This generally protects "[m]edical device manufacturers who subject their Class III devices to the rigorous premarket approval process" from state law claims "so long as they comply with federal law." *Bausch v. Stryker Corp.*, 630 F.3d 546, 550 (7th Cir. 2010).

But *Bausch* highlights that *Riegel* did not change the standard that state law claims based on federal violations are not expressly preempted by § 360k. *Id.* at 552. In *Bausch*, the Seventh Circuit stated that "federal law is clear: for manufacturers of Class III medical devices, the Quality System Regulations and Current Good Manufacturing Practices adopted by the FDA under its delegated regulatory authority are legally binding requirements . . . ." The Court further emphasized that "[t]he failure to comply with any applicable provision in this part [of the regulations] renders a device adulterated under section 501(h) of the act" and open to regulatory

action. *Id.* at 555 (citing 21 C.F.R. § 820.1). The Court added that in Class III medical device cases, potentially valuable information related to Premarket Approval is kept confidential and formal discovery may be required before a plaintiff can identify specific defects. *Comella v. Smith & Nephew, Inc.*, 2013 WL 6504427, at *3 (N.D. Ill. Dec. 11, 2013) (citing *Bausch,* 630 F.3d at 560).

Here, because the device was granted Premarket Approval, the federal government did establish requirements applicable to the device. Since federal requirements exist, to survive the motion to dismiss, Lloyd must plead state law claims plausibly showing that Medtronic deviated from the premarket approval requirements specific to the device. Lloyd's Complaint—which shows deviations identified by the FDA for adulteration and recalls specific to pump manufacturing—plausibly alleges facts sufficient to demonstrate that Medtronic deviated from Premarket Approval requirements and that at least some of those deviations were with respect to the device. Moreover, the Complaint plausibly shows the existence of manufacturing defects caused by violations of federal regulations connected to the device and parts implanted in Lloyd that failed to deliver medication, causing the injuries.[2]

Plaintiffs alleging specific defects relating to Class III medical devices can face greater difficulty in pleading, and their burden is contingent on the amount of information they have access to. *Comella*, 2013 WL 6504427, at *3 (citing *Bausch,* 630 F.3d at 561). Simply put, Lloyd assembled the minimum factual

[2] The Court, however, does not find Lloyd's misbranding allegations plausible.

grounding to meet the plausibility standard and the Complaint alleges parallel state law claims that comply with Rule 8.

That said, because Counts II, IV, and V are merely duplicative of the previous counts, the Court dismisses those count as redundant.

CONCLUSION

For the reasons set forth above, Defendant Medtronic's Motion to Dismiss (Doc. 31) is **GRANTED in part** and **DENIED in part**. The Court denies the motion as to Counts I, III, and VIII, but grants the motion as to Counts II, IV, and V. Counts II, IV, and V are **DISMISSED with prejudice**. Plaintiff Gina Lloyd has 7 days to file an amended complaint that reflects the dismissed counts and other findings in this Order.

IT IS SO ORDERED.

DATED: July 7, 2021

s/ Stephen P. McGlynn
STEPHEN P. McGLYNN
U.S. District Judge